

The following claims are pending in the present application: Claims 6–13. Claim 7 is presently withdrawn as directed to non-elected subject matter.

No amendment is requested herein.

I. Rejection under 35 U.S.C. §103(a)

Claims 1–6 and 8–13 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over D'Angelo & Schur (U.S. Patent No. 5,932,240, herein "D'Angelo") in view of D'Angelo [*sic*]. Applicant believes the second reference to "D'Angelo" in the present rejection is a typographical error and that the Examiner intended Lauterbach *et al.* (U.S. Patent Application Publication No. 2003/0027793, herein "Lauterbach") to be the secondary reference. This rejection is respectfully traversed.

No admission is made herein that Lauterbach (mis-spelled "Lauterback" in the cited document) constitutes prior art to the present invention. It is noted that Lauterbach is not statutory prior art against the present invention, having published after the priority date of the present application. Applicant reserves the right to disqualify this publication as prior art; however, the question is moot. As shown below, even if Lauterbach were available as prior art, a *prima facie* case of obviousness cannot be sustained over D'Angelo in view of Lauterbach.

Under *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007), a claimed invention is considered obvious if the differences between the invention of the claim and the prior art are such that the subject matter of the invention of the claim as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

To reach a proper determination under 35 U.S.C. §103, the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the Examiner must then make a determination whether the claimed invention as a whole would have been obvious at that time to that person. Knowledge of Applicant's disclosure must be put aside in reaching this determination. MPEP 2142.

In discussing the combination of D'Angelo and Lauterbach, the present Action states

that it would have allegedly been obvious to a person of skill in the art “to add rotigotine free base to the transdermal delivery system . . . because D’Angelo suggest that drugs used to treat Parkinson’s disease may be included in the microreservoirs of the transdermal patch” (Action, p. 8, lines 14–22). However, the Action fails to acknowledge that parkinsonism control agents are mentioned in D’Angelo as only one class of drugs, embedded within a large list of other possible pharmacological actives. Furthermore, rotigotine is not mentioned in D’Angelo’s list of exemplary parkinsonism control agents (*i.e.*, bromotriptine, percolide, and anticholinergics including benztropine, pro-cyclidine and amantadine). Nothing in D’Angelo would motivate one of ordinary skill to select rotigotine free base over any other pharmacological agent. In fact, the exemplary list of drugs is prefaced with the statement that “almost any drug, to some degree, can be administered transdermally” (D’Angelo, col. 1, lines 58–59). Therefore, Applicant submits that the combination of D’Angelo and Lauterbach can only be made, impermissibly, by hindsight reconstruction of the invention based on the disclosure of the present specification. Applicant submits that, at least for this reason, a *prima facie* case of obviousness has not been established.

All claim limitations must be considered in judging the patentability of a claim against the prior art. MPEP 2143.03. Even if a sound rationale for combining the references has been articulated (which is not admitted herein), the resulting combination fails to teach or suggest all claim limitations. If the references are missing claimed features, there must be some apparent reason either in the references or the general knowledge in the art to modify the references to include the missing subject matter. *KSR, supra*.

According to Claim 1, the transdermal delivery system comprises a multitude of microreservoirs within a self-adhesive matrix, wherein the microreservoirs have a maximum diameter that is less than the thickness of the self-adhesive matrix. As described in more detail below, the combination of references fails to teach or suggest, at least, (a) microreservoirs within a self-adhesive matrix and/or (b) microreservoirs having a maximum diameter that is less than the thickness of the layer wherein they are embedded. For at least these reasons, a *prima facie* case of obviousness has not been established.

1.1. No teaching or suggestion of microreservoirs within a self-adhesive matrix

The present Action (pp. 6–7) cites D’Angelo as allegedly disclosing an acrylate-based self-adhesive layer. However, without admitting that the “microcapsules” of D’Angelo necessarily equate to “microreservoirs” as recited in the instant claims, Applicant respectfully points out that the acrylate adhesive recited by D’Angelo is not the matrix within which microcapsules are incorporated, but a separate adhesive border used to adhere the patch to the skin. The “self-adhesive layer” referenced in the Action at p. 7, line 1 is misleading; the acrylate adhesive in D’Angelo is not a layer that either contains the microcapsules or lies over or under the microcapsule-containing layer. Rather it occurs in a border around the patch (D’Angelo, col. 8, lines 52–55).

The present Action (p. 8) states that it would have allegedly been obvious to add the rotigotine free base of Lauterback to the “microreservoir component of the transdermal formulation taught by D’Angelo”. However, even if one of skill in the art would have been motivated to make such a modification (which is not admitted herein), that modification would not have provided microreservoirs within a self-adhesive matrix, as required by Claim 1.

The fact that D’Angelo mentions an acrylate adhesive and microcapsules as independent components of a patch is not sufficient to establish a *prima facie* case of obviousness. Under *KSR, supra* (emphasis added), “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. ... [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” The present Action’s identification of a reference with microcapsules and a self-adhesive acrylate, each discussed independently in the reference, is exactly the type of hindsight reconstruction warned against in *KSR*. The combination of documents cited in the present Action does not provide an apparent reason for a person of ordinary skill to select and modify elements from the collective teachings to arrive

at the present invention. See *Id.* (an obviousness inquiry includes determining whether there was an apparent reason to combine the known elements in the fashion claimed).

No reason has been articulated to embed microreservoirs within the self-adhesive border as opposed to a gel matrix layer as disclosed by D'Angelo.

1.2. No teaching or suggestion of microreservoirs having a maximum diameter less than the thickness of the layer wherein they are embedded

D'Angelo fails to teach a transdermal system wherein the microreservoirs have a maximum diameter that is less than that of the self-adhesive layer. In stating (Action, pp. 9–10) that it would allegedly be within the level of ordinary skill in the art to manipulate the size of microreservoirs, the Examiner fails to recognize that Claim 1 requires more than simple manipulation of microreservoir diameter or thickness of a self-adhesive matrix layer. Specifically, Claim 1 requires a microreservoir diameter less than a maximum value relative to the thickness of the self-adhesive matrix layer.

Nothing in D'Angelo suggests that it would be beneficial for the microcapsules to have a maximum diameter less than the thickness of the matrix layer (in D'Angelo a gel matrix layer, not a self-adhesive matrix layer) in which they are embedded. Where relativity of microcapsule diameter and gel matrix layer is disclosed at all, it is clear that the microcapsules are contemplated by D'Angelo to be exposed to the surfaces of the matrix layer, *i.e.*, to have a diameter that is not smaller than the thickness of the matrix layer. Specifically, in D'Angelo's description of Figs. 1 and 2 thereof, a layer of microencapsulated medicament is said to be "adhered to the bottom of a tear strip 5 and to the top of a permeable membrane 13 by microcapsule adhesive 19" (col. 8, lines 3–6). That the microcapsules themselves adhere to layers above and below the matrix layer is clear from Fig. 2. D'Angelo further emphasizes a means for disrupting the microcapsules, which in some embodiments is achieved by pulling back the tear strip, to which the "frangible" microcapsules are adhered (col. 8, lines 34–39). One of ordinary skill would be de-motivated, by the teaching of D'Angelo regarding the significance of the disruption mechanism, to reduce the diameter of the microcapsules, such that the microcapsules no longer contact the layers above and below the matrix in which they are embedded.

Therefore, D'Angelo not only fails to disclose, but indeed teaches away from, a matrix layer containing microreservoirs of diameter smaller than the thickness of the matrix layer. Proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. MPEP 2145.X.D.3, citing *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).

Further, a modification of D'Angelo to reduce the size of the microcapsules, far from being a routine modification as stated in the Action (pp. 9–10), would render the patch of D'Angelo unsatisfactory for its intended purpose. “If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01.V, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If microcapsule diameter were reduced so that the microcapsules no longer adhered to the tear-off strip, the patch of D'Angelo would no longer function as intended.

Alternatively, a modification of D'Angelo to reduce the size of the microcapsules would change the principle of operation of the D'Angelo patch. “If the proposed modification ... would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP 2143.01.VI, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). If microcapsule diameter were reduced so that the microcapsules no longer adhered to the tear-off strip, the principle of operation of D'Angelo would be changed, indeed lost.

1.3. Lauterbach fails to supply the missing features

The secondary reference, Lauterbach, does not supply either one of the essential features of the present invention that are missing from D'Angelo, namely (a) microreservoirs within a self-adhesive matrix or (b) microreservoirs having a maximum diameter that is less than the thickness of the layer wherein they are embedded. Lauterbach, indeed, has no teaching or suggestion of microreservoirs at all. Thus no combination of the cited documents teaches or suggests all the claim limitations.

1.4. Rejection under 35 U.S.C. §103(a): conclusion

For any one of the reasons set forth above, a *prima facie* case of obviousness has not been established for instant Claim 1.

Notwithstanding the Examiner's remarks with respect to the subject matter of dependent Claims 2-6 and 8-13, these claims each embody all the limitations of Claim 1 from which they depend or which they reference, and are therefore nonobvious at least for the same reasons that Claim 1 is nonobvious. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. MPEP 2143.03.

However, Applicant wishes to clarify the Examiner's statements regarding PVP and the addition of silicone adhesives, as these statements appear again to utilize the hindsight reconstruction warned against in *KSR, supra*. Specifically, the present Action (p. 9, lines 12-16) alleges "that D'Angelo *et al.* teach PVP, which overlaps with the instantly claimed crystallization inhibitor." Applicant submits that the discussion of PVP in D'Angelo is focused on use of PVP as a matrix and not as a component of the microcapsules. Therefore, any combination of D'Angelo and Lauterbach (even if motivation existed for such combination, which, as shown above, is not the case) would not result in microcapsules containing PVP as a crystallization inhibitor, but as a matrix in which the microcapsules are incorporated. Furthermore, the Action (p. 9, lines 4-9) alleges that "it would have been obvious to a person of skill in the art to add a silicone pressure adhesive as taught by Lauterbach *et al.* to the adhesive component of the transdermal formulation for additive adhesive effect." Even if this were true, which is not admitted, addition of self-adhesive silicone to the adhesive component of the D'Angelo patch would not result in microcapsules within a self-adhesive matrix, but simply in additional self-adhesive for the patch border to adhere the patch to the skin.

Withdrawal of the present rejection under 35 U.S.C. §103(a) is respectfully requested for at least the reasons given above.

2. Provisional obviousness-type double patenting rejections

2.1. Double patenting over Serial No. 10/429,283 in view of D'Angelo

Claims 1-6 and 8-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 5-16 of copending application Serial No. 10/429,283, in view of D'Angelo. This rejection is provisional because the allegedly conflicting claims have not yet been patented.

The present rejection is respectfully traversed, at least for the following reason. Each of Claims 1–6 and 8–13 of the present rejection requires that the TDS self-adhesive matrix comprise a multitude of rotigotine-containing microreservoirs having a maximum diameter that is less than the thickness of the matrix. This limitation is not taught or suggested by the reference claims, nor is any disclosure found in D'Angelo that would correct this deficiency. Indeed, as shown above, it is important to D'Angelo's system that microcapsule diameter be not less than the thickness of the matrix wherein the microcapsules are embedded.

At least the distinguishing features mentioned above are therefore sufficient to create patentable distinction over Claims 5–16 of the '283 application, even in view of D'Angelo.

2.2. Double patenting over Serial No. 10/627,990 in view of D'Angelo and Lauterbach

Claims 1–6 and 8–13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 1–13 of copending application Serial No. 10/627,990, in view of D'Angelo and Lauterbach. This rejection is provisional because the allegedly conflicting claims have not yet been patented.

The present rejection is respectfully traversed, at least for the reason that the present application has an earlier filing date (July 22, 2003) than the reference application (July 28, 2003), and therefore, when issued as a patent, will expire before any patent that issues from the reference application. Rejection for double patenting is warranted only where “issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent” (MPEP 804.II.B.1). That is not the case here.

Applicant notes that a terminal disclaimer was filed in the '990 application on July 29, 2008.

3. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the present Action and that the Application is in condition for allowance.

If personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. §1.97(c)(2)

Applicant hereby submits an Information Disclosure Statement (IDS) under 37 C.F.R. §1.97(c)(2) after the mailing of a first Office Action on the merits in the above referenced application. This IDS further supplements the IDS submitted on February 20, 2008.

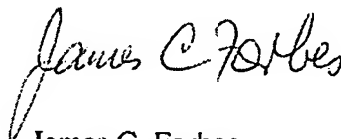
In accordance with 37 C.F.R. §1.97(g) and (h), this submission shall not be construed as representation that a search has been made or as admission that information presented or cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

In accordance with 37 C.F.R. §1.98, Applicant submits herewith (1) a listing on Form PTO-1449 of documents requested to be considered by the Examiner and (2) a legible copy of each listed document, except for U.S. patents and U.S. patent application publications.

Consideration by the Examiner of the present submission is requested.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.



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Attachment
Form PTO-1449